



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0880]

Karen L. Blyth: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Karen L. Blyth for a period of 20 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Blyth was convicted, as defined in section 306(l)(1)(B) of the FD&C Act (21 U.S.C. 335a(l)(1)(B)), of 10 felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Blyth was given notice of the proposed debarment and an opportunity to request a hearing within the time frame prescribed by regulation. As of March 23, 2012 (30 days after receipt of the notice), Ms. Blyth had not responded. Ms. Blyth's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade,
Office of Regulatory Affairs,
Food and Drug Administration,
12420 Parklawn Drive,
Rockville, MD 20857,
301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On May 4, 2011, Ms. Blyth was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Southern District of Alabama accepted her plea of guilty and entered judgment against her for the following offenses: One count of conspiracy to commit offenses against the laws of the United States, in violation of 18 U.S.C. 371; nine counts of false labeling under the Lacey Act, in violation of 16 U.S.C. 3372(d)(2) and 3373(d)(3)(A); two counts of receipt of merchandise imported contrary to law, in violation of 18 U.S.C. 545; and one count of misbranding, in violation of 21 U.S.C. 331(a), 333(a)(2) and 343(a)(1) and (b).

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the importation into the United States of any food. The

factual basis for these convictions is as follows: As stated in the factual resume accompanying the plea agreement referenced above and alleged in the indictment filed against Ms. Blyth, Ms. Blyth was a co-owner, president, and treasurer of CSE Inc., which was used to buy and sell seafood. She was also a co-owner, president, and chief executive officer of RF Inc. from on or about October 1, 2004, through on or about March 2007. RF Inc. also sold seafood, including but not limited to shrimp, oysters, Lake Victoria perch, and types of catfish, commonly called basa, swai, and sutchi.

Beginning on or about January 1, 2004, and continuing through on or about November 8, 2006, Ms. Blyth knowingly, willingly, and unlawfully combined, conspired, confederated, and agreed with her coconspirators to commit offenses against the laws of the United States related to importation of food. This conduct was in violation of 18 U.S.C. 371. Specifically, Ms. Blyth received and bought 81,000 pounds of fish of the genus Pangasius (a type of catfish commonly called basa, swai, or sutchi) that she knew had been unlawfully imported from Vietnam. She knew that the fish was falsely labeled as sole when it was imported, and that it was imported without the required antidumping duty having been paid. She created or caused others to create false invoices and labeling for this fish, and other fish of the genus Pangasius bought and sold to customers, totaling approximately 101,078 pounds. Ms. Blyth sold and invoiced the fish as grouper or sole, allowing her to sell the fish in interstate commerce at higher profit margins and more readily than if the fish had been accurately labeled and described.

From on or about February 9, 2005, through on or about June 27, 2005, Ms. Blyth knowingly made and caused to be made a false record, account, and label for, and false identification of fish, that had been and was intended to be transported in interstate and foreign commerce, having a market value greater than \$350, and that involved the sale and purchase, the

offer of sale and purchase, and the intent to sell and purchase fish, and the importation of fish, in that she created and caused to be created invoices, boxes, and other documents that falsely identified the fish. Specifically, Ms. Blyth falsely identified fish as sole and Cynoglossus bilineatus, when in fact it was fish of the genus Pangasius, a type of catfish. This conduct was in violation of 16 U.S.C. 3372(d)(2) and 3373(3)(A).

From about March 30, 2005, through April 4, 2005, Ms. Blyth knowingly received, concealed, bought, sold, and facilitated the transportation, concealment, and sale of merchandise after importation, specifically frozen fish fillets of the genus Pangasius, knowing it to have been imported and brought into the United States contrary to law, that is falsely declared and with applicable duties having been paid. This conduct is in violation of 18 U.S.C. 545.

From approximately March 30, 2005, through approximately June 22, 2005, with intent to defraud and mislead, Ms. Blyth introduced and delivered and caused to be introduced and delivered into interstate commerce food, specifically frozen fish fillets, that was misbranded in that it had been falsely and misleadingly labeled and described as sole and Cynoglossus bilineatus, when in fact the fish was of the genus Pangasius. This conduct in violation of 21 U.S.C 331(a), 333(a)(2) and 343(a)(1) and (b).

As a result of her conviction, on February 17, 2012, FDA sent Ms. Blyth a notice by certified mail proposing to debar her for a period of 20 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Blyth was convicted of 10 felony counts under Federal law for conduct relating to the importation into the United States of an article of food because she: Conspired to and committed offenses related to the importation of fish into the United States; falsely identified fish; concealed, bought, sold, and facilitated the transportation,

concealment, and sale of frozen fish fillets after importation, knowing it to have been imported and brought into the United States contrary to law; and introduced and delivered misbranded fish into interstate commerce. The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act (21 U.S.C. 335a(c)(3)) that Ms. Blyth should be subject to a 20-year period of debarment. The proposal also offered Ms. Blyth an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Blyth failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Ms. Karen L. Blyth has been convicted of 10 felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that she is subject to a 20-year period of debarment.

As a result of the foregoing finding, Ms. Blyth is debarred for a period of 20 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Ms. Blyth is a prohibited act.

Any application by Ms. Blyth for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) should be identified with Docket No. FDA-2011-N-0880 and

sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 24, 2012

Armando Zamora,
Acting Director,
Office of Enforcement,
Office of Regulatory Affairs.

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